Mig™

Mirogabalin Besylate INN Film Coated Tablet

DESCRIPTION

Mig™ is a preparation of Mirogabalin, a gamma-aminobutyric acid (GABA) derivative. It is a potent and specific ligand of the α2δ subunit of voltage-dependent Ca2+ channels that inhibits calcium ions influx and suppresses the release of neurotransmitters in the nervous system to reduce pain. It is usually used for treating diabetic peripheral neuropathic pain and postherpetic neuralgia.

INDICATIONS

• Diabetic peripheral neuropathic pain (DPNP) • Postherpetic neuralgia (PHN)

DOSAGE AND ADMINISTRATION

In general, for adults, the initial dose of mirogabalin is 5 mg orally twice daily, and then the dose is gradually increased by 5 mg at intervals of 1 week or longer to 15 mg orally twice daily. Depending on age and symptoms, the dosage may be adjusted appropriately within the range of 10 to 15 mg at a time, and the dose should be administered twice daily.

If you miss a dose, take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should never take two doses at one time. If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist. Do not stop taking this medicine unless your doctor instructs you.

ADMINISTRATION IN RENAL IMPAIRMENT

No dose adjustment is recommended in mild renal impairment. Reduce to 50% dose in moderate renal impairment. Reduce to 75% dose in severe renal impairment and End-Stage Renal Disease (ESRD) patients.

		Degree of Renal Dysfunction (CLcr: mL/min)		
		Mild (90 > CLcr ≥ 60)	Moderate (60 > CLcr ≥ 30)	Severe (including hemodialysis patients) (30 > CLcr)
Daily dose		10 - 30mg	5 - 15mg	2.5 - 7.5mg
Initial dose		5 mg twice a day	2.5 mg twice a day	2.5 mg once a day
Effective dose	Minimum dose	10 mg twice a day	5 mg twice a day	5 mg once a day
	Recommended dose	15 mg twice a day	7.5 mg twice a day	7.5 mg once a day

SPECIAL CONTRAINDICATIONS

Age (adult and elderly) did not significantly affect the PK of mirogabalin.

Following oral administration of a single 5 mg dose of mirogabalin in subjects with different grade of renal impairment, mirogabalin AUC_t was approximately 1.33-fold, 1.90-fold, 3.64-fold and 5.25-fold in subjects with mild, moderate, severe renal impairment and end stage renal disease (ESRD), respectively, relative to healthy controls. C_{max} increased with increasing severity of renal impairment, the degree of increase was less than that of AUC_t. 15.3% of dosed mirogabalin was removed from blood during 4-hour hemodialysis in ESRD patients. No dose adjustment is recommended in mild renal impairment. Reduce the 50% dose in moderate renal impairment. Reduce the 75% dose in severe renal impairment and ESRD patient.

C_{max} was approximately 1.04-, and 0.85-fold and AUC_{inf} was approximately 0.88-, and 1.10-fold in subjects with mild and moderate hepatic impairment, respectively, relative to healthy controls after single oral dose of 15 mg. No dose adjustment is recommended in mild or moderate hepatic impairment. No PK data of mirogabalin are available for severe hepatic impairment subject.

SIDE EFFECTS

• Somnolence • Dizziness • Weight gain • Nasopharyngitis • Peripheral Edema

PRECAUTION AND WARNING

Mirogabalin may impair the ability to drive or operate machinery. Elderly people should be aware of falling and fracture.

USE IN PREGNANCY AND LACTATION

No available data. Mirogabalin may only be used in pregnant and lactating women if the expected therapeutic benefits outweigh the possible risks associated with treatment. It is recommended to consult with a healthcare provider before using Mirogabalin during pregnancy and lactation.

USE IN CHILDREN AND ADOLESCENTS

No information is available on the use of Mirogabalin in children and adolescents. The clinical studies conducted on Mirogabalin were in adult populations only. Therefore, the safety and efficacy of Mirogabalin in children and adolescents have not been established. Mirogabalin is only approved for use in adults.

DRUG INTERACTION

Co-administration with OAT1, OAT3, OCT2, MATE1, MATE2-K, or UGT inhibitors may increase Mirogabalin exposure, so it should be used with caution. Mirogabalin did not inhibit or induce major human CYP molecular species and did not inhibit activities of drug transporters (including OAT1, OAT3, OCT1, OCT2, OATP1B1, OATP1B3, MATE1, MATE2-K, P-gp, and BCRP). However, consulting with a healthcare provider before using Mirogabalin with other medications is recommended.

OVERDOSAGE

Repeated-dose toxicity studies showed that the dose-limiting toxicity was considered abnormal clinical signs associated with CNS depression, resulting from exaggerated pharmacological action. Therefore, using Mirogabalin cautiously and following the recommended dosing regimen is advised. In case of a suspected overdose, it is recommended to seek medical attention immediately.

STORAGE

Do not store above 25 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Mig™ 2.5 tablet:
Box containing 2 strips of 10 tablets each. Each film-coated tablet contains Mirogabalin Besylate INN equivalent to Mirogabalin 2.5 mg.

Mig™ 5 tablet:
Box containing 2 strips of 10 tablets each. Each film-coated tablet contains Mirogabalin Besylate INN equivalent to Mirogabalin 5 mg.

Mig™ 10 tablet:
Box containing 1 strip of 10 tablets. Each film-coated tablet contains Mirogabalin Besylate INN equivalent to Mirogabalin 10 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
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TM TRADEMARK
PM09148 V01